

REMARKS

Applicant respectfully requests entry of the Amendment and reconsideration of the claims. Claim 1 has been amended. Support for this amendment can be found at page 3, lines 11 to 21 and line 32 to page 4, line 4. Please cancel claims 6 and 23-28 without prejudice. Applicant reserves the right to file one or more divisional applications to claim the cancelled subject matter. Applicants respectfully request reconsideration and withdrawal of the pending rejections under 35 U.S.C. § 103(a) and § 112, first paragraph.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 6 is rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. Claim 6 has been cancelled and as such, this rejection is now moot.

Rejections under 35 U.S.C. § 103(a)

Claims 1-5, 7-13, and 22 are rejected under 35 U.S.C. § 103(a) as allegedly obvious over Cuckler et al. (*J. Bone Joint Surg. Am.*, 1985) in view of EP 100673 (Stracher). Claims 14-20 are rejected under 35 U.S.C. § 103(a) as allegedly obvious over Cuckler et al. in view of EP 100673 as applied to claims 1-5, 7-13 and 22, and in further view of Wan et al. (*J. Thorac. Cardiovasc. Surg.*, 1996), Sellevold et al. (*Anesth. Analg.*, 1995), and Atsma et al. (*Circulation Research*, 1995). Claim 21 is rejected under 35 U.S.C. § 103(a) as allegedly obvious over Cuckler et al. in view of EP 100673 as applied to claims 1-5, 7-13 and 22 above, and in further view of Young (“Current treatment for Human Spinal Cord Injury”). Applicant respectfully traverses the Examiner’s rejections.

To establish a *prima facie* case of obviousness, the teachings of the prior art should have suggested the claimed subject matter to the person of ordinary skill in the art, and all the claim limitations must be taught or suggested in the references cited by the Examiner. *In re Kotzab*, 217 F.3d 1365, 1370 (Fed. Cir. 2000). As articulated by the Supreme Court, a combination is obvious if it is no more than the predictable use of known elements according to their established functions; and there was a reason to combine the known elements. *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. ___, 127 S. Ct. 1727 (2007). To make a *prima facie* case of obviousness, “it remains

necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed.” *Id.* Applicant respectfully submits that the Examiner does not make a *prima facie* case of obviousness because there is no motivation to combine all of the claim elements.

In making the various rejections under § 103(a), the Examiner has established the Cuckler et al. article as a basis for all of the rejections. As the Examiner has recited, Cuckler et al. disclose the administration of procaine and methylprednisone to patients with a clinical diagnosis of acute herniated nucleus pulposus or spinal stenosis. However, Cuckler et al. explicitly state “[t]his study ***did not demonstrate any therapeutic efficacy of epidural methylprednisolone acetate*** in the treatment of either acute or chronic neural compression syndromes in the lumbar spine” (page 66, col. 1, first sentence of the Discussion) [emphasis added]. In view of this conclusion, Applicant respectfully asserts that there is no motivation to combine Cuckler et al. with any of the other cited art to arrive at the claimed therapeutically effective amounts of said compounds.

Specifically, Cuckler et al. teach away from the instant claims. "A reference may be said to teach away when a person of ordinary skill, upon [examining] the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). Since Cuckler et al. teach that methylprednisone is not therapeutically effective to treat nerve tissue, Applicant asserts that a person of ordinary skill of the art would not seek to combine methylprednisone with other compounds to treat damaged nerve tissue. Thus, the basis art cited by the examiner in the pending obviousness rejections actually teaches away from the claimed subject matter.

In view of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a).

Summary

For the reasons set forth above, the applicant believes that all of the pending rejections have been adequately addressed and that the present claims are in condition for allowance, which action is respectfully requested. The Examiner is invited and encouraged to contact the undersigned directly if such contact will expedite the prosecution of this application to issue.

Respectfully submitted,

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